

Remarks

In view of the above amendments and the following remarks, reconsideration of the outstanding office action is respectfully requested.

Claims 1-6 and 22-27 are under examination. Claims 7-21 have been withdrawn as being drawn to a non-elected species. Claims 1 and 26 are amended, claim 24 is canceled, and claims 28-34 are new. Support for the new and amended claims is found at paragraphs [0039] - [0041] and [0043]. No new matter has been added.

The rejection of claims 1-6 and 22-27 under 35 U.S.C § 103(a) for obviousness over WO 02/45711 A1 to Bannister et al. (“Bannister”) and further in view of U.S. Patent No. 6,171,298 to Matsuura et al. (“Matsuura”) is respectfully traversed.

Bannister relates to the simultaneous, sequential, or separate use of an anti-muscarinic agent and a calcium channel blocker in the treatment of a muscle tone disorder or a proliferative, inflammatory, or secretory condition. Anti-muscarinic agents that can be used in this invention include tiotropium. Bannister also discloses that the active agent may be used in therapy where the condition to be treated involves urinary incontinence. Bannister discloses topical use of anti-muscarinic agents either dermally to the lung or to the gastrointestinal tract. However, Bannister fails to mention or suggest administering anti-muscarinic agents intravesically as required by the claimed invention.

Matsuura relates to a drug-infusing device which is implanted in a bladder. The device is implanted in an unflated, low profile state. After insertion, the device is filled with a substance such as a drug and assumes an increased profile. Antimuscarinic agents may be used in the device. The device delivers the drug at controlled rate over an extended period of time using a pressure responsive valving member. The flow resistance of the valving member is responsive to the pressure at which the drug is stored. The resistance of the valving member decreases as the pressure within the infusing device decreases to provide a controlled flow rate. Matsuura fails to disclose the use of an additive which enhances the adherence of the claimed compound to the subject's bladder wall and prolongs duration of action.

In the outstanding office action, the U.S. Patent and Trademark Office (“PTO”) asserts that it would have been obvious to a skilled artisan to incorporate the antimuscarinic agents of Bannister into Matsuura's intravesical instillation or infusion device to achieve the claimed method of treating bladder disease and avoid the side effects

associated with systemic administration. Even if this were true, the combination of these references does not teach the claimed invention.

Bannister does not involve intravesical administration at all. Although Matsuura administers a therapeutic compound intravesically, it does not utilize an additive which enhances adherence of the compound to the bladder wall and prolongs duration of action compared to when the compound is not in a composition containing the additive. Instead of utilizing such an additive to enhance adherence to the bladder wall, Matsuura employs a drug infuser device to controllably release the drug. The implantation and use of such a device is substantially different from applicants' composition where the additive prolongs duration of action and enhances adherence to the bladder wall. The combination of Bannister and Matsuura likewise fails to teach the specific features of claims 28-34.

The PTO's reference to the paragraph bridging columns 19 and 20 of Matsuura as teaching the use of polysaccharide coatings on the drug-infusing device to prevent or reduce encrustation does not overcome the above-noted deficiencies of this reference. In particular, such coatings are referred to in Matsuura as surface pretreatments to remain on the drug-infusing device so that encrustation and infection are prevented. This is far different than the claimed additive which is in a composition also including a therapeutic amount of certain compounds where the additive acts on the bladder wall and to prolong duration of action of the compounds.

Accordingly, the rejection of claims 1-6 and 22-27 for obviousness is improper and should be withdrawn.

In view of all of the foregoing, applicant submits that this case is in condition for allowance and such allowance is earnestly solicited.

Respectfully submitted,

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